UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,603	09/29/2005	Ijeoma Uchegbu	4938-P03604US00	4005

110 7590 09/25/2009

DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
09/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,603	UCHEGBU ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,33,34,44-47,51,52 and 55-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,33,34,44-47,51,52 and 55-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Response Dated June 22, 2009

1. Claims 1-4, 33-34, 44-47, 51-52 and 55-62 are pending. An action on the merits of claims 1-4, 33-34, 44-47, 51-52 and 55-62 is contained herein below.

2. The rejection of claims 1-4, 33-34, 44-47, 51-52 and 55-62 under 35 U.S.C. 103(a) as being unpatentable over Kotze et al. Journal of Controlled Release (1998), Vol. 51, pages 35-46 (Kotze) and Schipper et al. Pharmaceutical Research (1997), Vol. 14, pages 923-929 (Schipper) in combination has been rendered moot in view of applicant's amendment dated June 22, 2009.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-4, 33-34, 44-47, 51-52 and 55-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchegbu et al. International Journal of Pharmaceutics (2001), Vol. 224, pages 185-199 (Uchegbu) and Wang et al. Langmuir (2001), Vol. 17, pages 631-636 (Wang) in combination.

Claims 1-4, 44-47 and 55-62 are drawn to a solubilizing carbohydrate polymer. Claims 33-34 are drawn to a method of forming a solubilizing carbohydrate polymer. Claims 51-52 are drawn to a method of dissolving poorly soluble drugs in a carbohydrate polymer.

Uchegbu teaches that soluble polymers bearing pendant amphiphilic or hydrophobic groups, commonly known as polysoaps have been studied for a number of years and numerous applications proposed based on exploiting their solubilisation capacity for hydrophobic molecules (pages 185-187). These compounds form intramolecular micelles usually several per molecule and their solubilisation capacity is not lost on dilution unlike small molecular weight micelles making them especially useful

as solubilisers. Polymeric micelles, prepared from block co-polymers have been used to improve the efficacy of drugs. Uchegbu presents a study reporting the unusual solubilisation behavior with a new type of chitosan-based polysoap—quaternary ammonium palmitoyl glycol chitosan (GCPQ) (Scheme 1). This compound, which may be used as a drug solubiliser, is found to form hydrophobic domains in solution and show hysteresis in its solubilisation behavior.

Uchegbu differs from the instantly claimed invention in that Uchegbu does not teach chitosan polymers having average molecular weight (MW) of about 2-30 kD; however, optimization of MW to enhance solubilisation properties would have been obvious and well within the purview of one of ordinary skill in the art as demonstrated by Wang.

Wang teaches that small weight amphiphiles such as phospholipids and synthetic surfactants have been known to assemble into bilayer vesicles and have been used as drug delivery systems (page 631). Polymeric unilamellar vesicles may be prepared from the amphiphilic polymer palmitoyl glycol chitosan (PGC) (Scheme 1) in which the hydrophobic pendant group is directly attached to the hydrophilic polymer backbone. Acid hydrolysis of glycol chitosan resulted in materials of different molecular weights (Table 1, Figure 1) (page 633). Increasing the acid degradation time decreased the molecular weight of the resulting polymer, and the commercially supplied glycol chitosan sample GC1 with a molecular weight of 242,000 could be degraded to one tenth of its molecular weight after 24 h, yielding a sample with a molecular weight of 26,000. All five PGC samples synthesized formed unilamellar vesicles on probe

sonicating their aqueous dispersions in the presence of cholesterol in a 2:1 weight ratio (Table 2, Figures 3 and 4). The reduction in vesicle size with a decrease in molecular weight indicates that the low molecular weight polymer variants afford the vesicles a higher degree of curvature than the higher molecular weight polymer (pages 635-636). A decrease in polymer molecular weight obtained by the acid hydrolysis of the chitosan-based polymer resulted in a decrease in vesicle size. The control on vesicle size offered by controlling molecular weight could be applied to other areas of polymer-based nanotechnology. This control on vesicle size will be especially useful to the area of drug delivery as vesicle size has a profound influence on drug biodistribution.

MW was known at the time of the invention to affect the solubilisation properties of chitosan polymers. Generally, differences in MW will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such MW is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Conclusion

7. Claims 1-4, 33-34, 44-47, 51-52 and 55-62 are pending. Claims 1-4, 33-34, 44-47, 51-52 and 55-62 are rejected. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patrick T. Lewis/
Primary Examiner, Art Unit 1623

/PL/